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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,810

01/17/2006

Marc Schwaller

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EXAMINER

MCCORMICK, MELENIE LEE

ART UNIT

PAPER NUMBER

1655

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
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3 MONTHS

01/23/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/23/2007.

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mailroom@bskb.com

Office Action Summary	Application No. 10/527,810	Applicant(s) SCHWALLER, MARC	
	Examiner Melenie McCormick	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Applicant's response with amendments filed 11/17/2006 has been considered.

New claims 17-22 have been added.

Claims 1-22 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating alopecia, acne, hirsutism, seborrhea, or body odor, does not reasonably provide enablement for preventing these conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants have reasonably described/disclosed that the instantly claimed method of administering the composition of claim 1 is useful for treating alopecia, acne, hirsutism, seborrhea, or body odor. However, the claim (see e.g. claim 16) encompasses using the claimed method for preventing such conditions. There are various forms of alopecia, acne, hirsutism, and seborrhea. As evidenced by Price (Seminars in Cutaneous Medicine and Surgery), the best outcome for one form of alopecia is a reduction in its progression, not absolute prevention (see e.g. Abstract). Please note that the term "prevent" is an absolute definition which requires a higher

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standard for enablement than does "treating", especially since it is well known in the medical art that the vast majority of medical conditions cannot be prevented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Deckers et al. (US 2002/0106337 A).

A composition comprising, in combination at least one marrow oil and at least one borage oil is claimed. Dependent claims are drawn to the composition wherein the marrow oil is extracted from the marrow pips and/or the borage oil is extracted from borage seeds, wherein the composition is formulated for topical application and wherein the composition is in the form of a medicinal product, a dermatological agent, a dermocosmetic agent, or a nutraceutical agent. Dependent claims are also drawn to the composition wherein the composition additionally comprises soybean extract.

Decker et al. teaches a composition which comprises oil bodies which are used for topical application to the human body (see e.g. [0002]). Decker et al. further teach that the oil bodies are derived from plant seeds, including borage and squash (marrow), and that the composition may comprise mixtures thereof (see e.g. [0053]). This reads on a composition comprising borage oil and marrow oil in combination wherein the

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marrow oil is extracted from the marrow pips and/or the borage oil is extracted from borage seeds, as instantly claimed. As evidenced by encarta.msn.com, pips are seeds (see e.g. encarta.msn.com). Decker et al. further teach that the composition may additionally comprise seed extract (oil) of soybean (see e.g. [0053]). Please note that the soybean oil extract would inherently contain isoflavones therein. Decker et al. also disclose that the composition is formulated for topical application for improvement or benefit of the physical appearance, health, fitness or performance of the surface area of the human body (see e.g. [0039]). This reads on a medicinal product, a dermatological agent, a dermocosmetic agent, or a nutraceutical agent, as instantly claimed.

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1- 3, 5-7, 9, 13, 15, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deckers et al. (US 2002/0106337 A).

A composition comprising, in combination at least one marrow oil and at least one borage oil is claimed. Dependent claims are drawn to the composition wherein the marrow oil is extracted from the marrow pips and/or the borage oil is extracted from borage seeds, wherein the composition is formulated for topical application, wherein the

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composition is in the form of a medicinal product, a dermatological agent, a dermocosmetic agent, or a nutraceutical agent, and wherein particular percentages by weight of the borage and/or marrow present. Dependent claims are also drawn to the composition wherein the composition additionally comprises soybean extract and wherein the soybean oil is present in particular percentages.

Deckers et al. beneficially teach a medicinal product, dermatological, dermocosmetic, or nutraceutical agent formulated for topical application which comprises marrow, borage, and soybean seed oil and is relied upon for the reasons set forth above.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a composition for topical preparation comprising borage and marrow seed oil and additionally comprising soybean seed oil, as instantly claimed. One of ordinary skill in the art at the time the claimed invention was made would have been motivated and would have had a reasonable expectation of success in doing so based upon the disclosure of Deckers et al. that such a composition has been prepared and is useful for improvement or benefit of the physical appearance, health, fitness or performance or the surface area of the human body (see e.g. [0039]). The adjustment of particular conventional working conditions (e.g. the result-effective adjustment of particular percentages by weight of the individual components of the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deckers et al. (US 6,146,645), Duranton et al. (US 6,465,421), Francis (US 5,695,748), and Segelman (US 6,017,893).

Deckers et al. (US 6,146,645) beneficially teach a composition for topical application which comprises soybean oil and/or cucurbita (marrow) oil, wherein the oil is obtained from seeds of the plant (see e.g. col 7, lines 35-46). Deckers et al. further teach that the composition is useful for combating hair loss and that the oil extract comprises 1-99% by weight of the composition (see e.g. col 14, lines 10-20). Deckers et al. also teach that the composition may be a food product (food composition or food supplement), a personal care product or a pharmaceutical product (nutraceutical agent) (see e.g. claim 25). Deckers et al. further teach that the composition may be a gum (see e.g. claim 26) or that it may be a cosmetic product, including, among other forms, a

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skin cream or a facial cream (which read on dermocosmetic/dermatological agent) (see e.g. claim 28).

Duranton et al. beneficially teach a composition which has hair growth-modulating properties (see e.g. col 1, lines 17-18). Duranton et al. further beneficially teach that the composition is intended to promote the growth of hair and that the composition contains borage oil (see e.g. claim 1). Duranton et al. also teach that the composition may be administered topically or orally (see e.g. col 6, lines 40-45).

Francis beneficially teaches a mixture (composition) which contains nettle and is used for restoring hair growth (see e.g. claim 1). It is further beneficially taught by Francis that the nettle can be in the form of a powder or a tea (which would be in a form suitable for oral administration) (see e.g. col 3, lines 13-16). Francis further teaches that the mixture is applied to the scalp (topical application) (see e.g. claim 1).

Segelman beneficially teaches a composition for preventing and treating hair loss (see e.g. col 1, lines 11-15). Segelman further beneficially teaches that the composition may be used topically or orally (see e.g. col 1, lines 60-65). It is further disclosed by Segelman that the composition is made from soybeans in powdered form and contains isoflavones (see e.g. col 7, example ii). Segelman also discloses that the topical forms of the composition include ointments, creams, lotions or other solutions, which read on a medicinal product, a dermatological agent, a dermocosmetic agent, or a nutraceutical agent (see e.g. col 6, lines 16-19). It is further disclosed by Segelman that the oral forms of the composition include capsules, tablets and powders (see e.g. col 6, lines 28-56).

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It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit- i.e. treating hair loss/alopecia -since each is well known in the art for the same purpose and for the following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose (as well as to use the combination for that purpose). The idea for combining them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). This rejection is based upon the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. The adjustment of particular conventional working conditions (e.g. the particular result effective concentration of each component or the particular part of the herb from which each extract is derived) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

With respect to the art rejection above, please note that "the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim (see e.g. claim 14) is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a

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different process.” In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

Response to Arguments

Claim Rejections - 35 USC § 103

Applicant's arguments, see pages 1-3 in view of the submission of the Verified English Translation of the priority document, French patent application No. 0211351 filed in France on September, filed on September 12, 2002, with respect to claims 1-16 have been fully considered and are persuasive. The rejection in the Office Action dated 08/17/2006 under 35 U.S.C 103 (a) of claims 1-16 has been withdrawn.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CHRISTOPHER R. TATE
PRIMARY EXAMINER